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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,778	04/20/2001	James N. Herron	3278.1US	3373

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,778	HERRON ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to Applicant's appeal brief filed August 30, 2004. Prosecution is re-opened to provide a new basis for rejection of claims 7 and 10-12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-9, 11, 13-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackowski, 5,747,274. Jackowski discloses a method evaluating the presence of a plurality of analytes in a sample, at least one analyte having known parameters indicative of an acute metabolic or disease state, see column 4, lines 32 - column 8, line 31, and column 19, lines 8-14; substantially simultaneously determining concentrations of each of the analytes; continuing the determination until the analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state, see column 29, lines 51-63; and reporting said determination in an amount indicative of the metabolic or disease state, see column 29, lines 51-63.

As to claim 2, evaluating the presence of at least one other analyte continues after the report in order to accurately determine the presence or concentration of the analyte, see column 22, lines 1-12.

As to claim 3, the method further comprises evaluating binding of the analytes to corresponding reactive elements over a plurality of time points, see column 22, lines 6-12.

As to claim 4, the determination is effected by reacting at least one analyte with a corresponding reactive element, see column 19 lines 15-22.

As to claim 5, the determination includes exposing the sample to the reactive elements, see column 11, lines 1-12.

As to claim 6, each reactive element is immobilized on a waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 8, the reactive elements are arranged in a pattern on the waveguide surface, (col. 30, line 67, col. 31, lines 8-9, and lines 15-16, see figure 10, disclosing the arrange of the antibodies, i.e., reactive elements.)

As to claim 9, the determination includes introducing a light beam including at least one wavelength for stimulating a light signal from the reactive element when the reactive element has coupled with the analyte, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 11, the determination includes measuring the light signal generated from the reaction of the analyte with the reactive element, see column 27, lines 37 column 28, line 11.

As to claim 13, the analyte is a marker released from cardiac tissue only after a myocardial infarction, see column 1, lines 63-67.

As to claim 14, the marker comprises myoglobin, see column 4, line 36-5.

As to claim 15, the analyte is a cardiac specific marker, see column 1, lines 63-67.

As to claims16-19, the analyte comprises troponin as claimed, see column 7, lines 34-37.

As to claim 20, the analyte comprises creatine kinase, see column 5, lines 29-31.

As to claim 21, the creatine kinase comprises CK-MB, see column 5, lines 29-31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackowski, 5,747,274, in view of Sawai et al., 4,224,304.

Jackowski discloses the invention substantially as claimed (see above.) Jackowski provides several examples of methods to determine the extent or amount of binding between the antibodies and markers (see for example, col. 28, lines 8-38.) Jackowski teaches that other methods for determining the presence and amount of a marker or analyte may be used in the invention (col. 29, lines 31-36.)

However, Jackowski does not disclose that the continuation step includes correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte (claims 7 and 12); nor that the light signal is indicative of a rate of reaction between the analyte of interest and the reactive element (claims 10 and 11.)

Sawai et al., 4,224,304, discloses a method for quantitative determination of antigens in a sample by evaluating the rate of increase in absorbance or percent absorption per unit time (col. 11, lines 36-44.) This method is a method of correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte, as well as a method wherein the light signal is indicative of a rate of reaction between the analyte and the reactive element as claimed by Applicant.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method taught by Sawai to determine the amount of analyte binding in the Jackowski method as a known alternative method for determining the extent or amount of binding between an antibody and an analyte. In view of the teachings of Jackowski and Sawai one of ordinary skill in the art would have a reasonable expectation of success.

Response to Arguments

Applicant's arguments in the brief are considered but are not persuasive.

Applicant argues on page 9 of the brief that Jackowski indicates that different analytes in a sample need not be evaluated concurrently. In response, Examiner

asserts that nevertheless the term "simultaneous" as used by Jackowski encompasses a concurrent evaluation of the sample, since Jackowski indicates that the term "simultaneous" includes an evaluation within a given period of time (col. 22, lines 8-9.) In any case, Applicant is claiming "**substantially** simultaneous" (emphasis added), which indicates that the evaluation need not be concurrently performed.

Applicant also argues on page 9 that Jackowski does not teach "continuing the determination until the analyte has been reliably determined to be present in an amount indicative of a disease. Applicant argues that "continuing" clearly indicates that the determination of the analyte is effected over a period of time, rather than at a single point in time. In response, Examiner asserts that the determination of the analyte is continued over a period of time until the analyte has been reliably determined to be present in an amount indicative of a disease (see col. 29, lines 54.) (The limitation "continuing the determination" does not require that several determinations of the amount of analyte present be performed over a period of time, but rather that the determination step be performed until the analyte has been determined to be present in a certain amount.)

Applicant also argues on page 10 that as to claim 2, Jackowski does not disclose "evaluating the presence of at least one other analyte in [a] sample may continue after a report of a reliable determination that at least one analyte in the sample is present in an amount which is indicative of a metabolic or disease state". Applicant argues that Jackowski teaches only evaluations of the presence of analytes in a sample at single points in time rather than continuously. Examiner emphasizes that the limitation refers

to "other analyte". Jackowski teaches an evaluation of the amount of three different markers. Thus, an evaluation of the second and third marker is the step of "evaluating the presence of at least one other analyte....after a report of a reliable determination...." In any case, Examiner emphasizes that Applicant recites "*may* continue" (emphasis added.) Thus, the reference only needs to disclose a method wherein "the evaluation...*may* continue after..." (emphasis added.)

Applicant also argues that Jackowski does not disclose the limitations of claim 8. The rejection of claim 8 has been clarified above to clearly indicate the pattern of antibodies, i.e., pattern of reactive elements, (see claim 8 above.)

As to claims 7 and 10-12, the arguments regarding these claims are moot in view of the new rejections above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
11/15/04